01-02-01

AF/GP/3723/#

PATENTS

PRT #12

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Nikolai M. Krivitski	Atty. Docket:	20850/40006 (old) 86017.000012 (New)
Serial No.:	09/241,455	Examiner:	Brian Szmal
Filed:	April 1, 1998	Art Unit:	3723

Title: METHOD AND APPARATUS FOR DETERMINING BLOOD FLOW DURING A VASCULAR ACCESS DYSFUNCTION CORRECTIVE PROCEDURE

APPELLANT'S BRIEF TRANSMITTAL

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Transmitted herewith in triplicate is an Appellant's Brief for this application under 37 C.F.R. §192.

Applicant is a Small Entity and the appropriate fee under 37 C.F.R. 1.17(c) is attached.

The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply.

Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and extension of time.

Respectfully submitted

Brian B. Shaw, Registration No. 33,782
Harter, Secrest & Emery LLP
700 Midtown Tower
Rochester, New York 14604-2070
(716) 232-6500

Date: December 29, 2000

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail No. EL603844625USl in an envelope addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231 on December 29, 2000.

Michele L. Hamby

1-9-01

PATENTS

#12

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Nikolai M. Krivitski	Atty. Docket:	20850/40006 (old) 86017.000012 (New)
Serial No.:	09/241,455	Examiner:	Brian Szmal
Filed:	April 1, 1998	Art Unit:	3723

Title: METHOD AND APPARATUS FOR DETERMINING BLOOD FLOW DURING A VASCULAR ACCESS DYSFUNCTION CORRECTIVE PROCEDURE

APPEAL BRIEF PURSUANT TO 37 CFR § 1.192

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

1. Real Party in Interest

The real party in interest to this appeal is the assignee of the application, Transonic Systems, Inc. of Ithaca, New York.

2. Related Appeals and Interferences

There are no other appeals or interferences known to appellant, appellant's legal representative or assignee which will directly effect or be directly effected by or having a bearing on the board's decision in the pending appeal.

3. Status of the Claims

There are 33 claims in the present application, all 33 claims are pending, and all 33 claims are subject to final rejection in the office action of May 18, 2000.

4. Status of Amendments

No amendments have been filed subsequent to the final rejection of May 18, 2000.

5. Summary of Invention

The present invention relates to an apparatus for determining blood flow in a vessel (page 1, lines 5-9; page 3, lines 15-24) comprising an elongate catheter (page 4, line 4; page 6, line 24; Figure 1) having a stenosis reducing member (page 4, lines 6-8; page 9, lines 4-12, Figures 1-3), a blood property change port (page 4, line 5; page 6, line 24; page 7, lines 3-24, page 11, line 11; reference 30 in Figures 2-6), and a downstream sensor spaced from the port for producing a signal corresponding to a blood property (page 4, line 5-6; page 6, line 24-25; page 12, line 16-17; reference 40 in Figures 2-6.

6. Issues

Whether Claims 1-33 are properly rejected under 35 U.S.C. §103(a) as being unpatentable over Quinn *et al.* (U.S. Patent No. 6,036,654) in view Tu *et al.* (U.S. Patent No. 6,053,913).

7. Grouping of Claims

Claims 1, 4, 6, 7 and 31 stand or fall together.

Claim 2 stands or falls alone.

Claim 3 stands or falls alone.

Claim 5 stands or falls alone.

Claim 8 stands or falls alone.

Claims 9, 12, 14 and 33 stand or fall together.

Claim 10 stands or falls alone.

Claim 11 stands or falls alone.

Claim 13 stands or falls alone.

Claim 15 stands or falls alone.

Claim 16 stands or falls alone.

Claim 17 stands or falls alone.

Claim 18 stands or falls alone.

Claim 19 stands or falls alone.

Claim 20 stands or falls alone.

Claim 21 stands or falls alone.

Claims 22 and 23 stand or fall together.

Claim 24 stands or falls alone.

Claims 25, 26 and 29 stand or fall together.

Claim 27 stands or falls alone.

Claim 28 stands or falls alone.

Claim 30 stands or falls alone.

Claim 32 stands or falls alone.

8. Argument

(i) Rejections under 35 U.S.C. §112, first paragraph

There are no outstanding rejections under 35 U.S.C. §112, first paragraph.

(ii) Rejections under 35 U.S.C. §112, second paragraph

There are no outstanding rejections under 35 U.S.C. §112, second paragraph.

(iii) Rejections under 35 U.S.C. §102

There are no outstanding rejections under 35 U.S.C. §102.

(iv) Rejections under 35 U.S.C. §103

Claims 1-33 stand rejected under 35 U.S.C. §103 as being unpatentable over Quinn *et al.* in view of Tu *et al.*.

Examiner Szmal relies upon Quinn, *et al.* to disclose a multi-lumen, multi-parameter catheter and its method of use that has:

1. a blood property change port and an aperture for introduction of a bolus into the blood stream;
2. a downstream sensor;
3. means for determining the blood flow rate from the signal generated from the sensor;
4. a heat source for generating a local temperature gradient;
5. the sensor and blood property change port sufficiently spaced apart to mix the dilution bolus through the port and blood flow;
6. introducing a blood property change upstream of the sensor and detecting the change in the blood property at the sensor and calculating the blood flow from the change in the blood property and passage of the change past the sensor;
7. a temperature gradient generator;
8. locating the blood property altering section within a vessel, locating the sensor downstream of the blood property altering section;
9. a plurality of blood parameter sensors in the vessel;
10. one of the sensors detecting an optical thermoelectrical chemical or physical property of the blood.

Examiner Szmal states that Quinn fails to disclose;

(a) The use of a catheter having a stenosis reducing member in order to perform a vascular corrective procedure;

(b) Inserting the catheter to the site of the stenosis;

(c) Reducing the stenosis in the vessel; and

(d) Performing angioplasty to reduce the stenosis in the vessel. [Paper 9, Page 3]

Examiner Szmal relies upon Tu, *et al.*. to disclose a rapid exchange stented balloon catheter that has ablation capabilities and its method of use, that has a catheter having a stenosis

reducing member in order to perform a vascular corrective procedure, inserting the catheter to the site of the stenosis, reducing the stenosis in the vessel and performing angioplasty to reduce the stenosis in the vessel. [Paper 9, page 3]

Based upon this, Examiner Szmal states "Since both Quinn, *et al.* and Tu, *et al.* disclose catheters that can be used in vascular corrective procedures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Quinn, *et al.* to include the use of an angioplasty or other corrective procedures, per the teachings of Tu in order to provide a device and method that would allow a cardiac surgeon to determine the blood flow at the site of the stenosis and perform the corrective procedure with the use of a single catheter instead of changing catheters in order to perform the procedure." [Paper 9, Page 3]

Claim 1

There is no explicit rejection of Claim 1 in Paper 9. Therefore, applicant assumes pages 2 and 3 of Paper 9 are to be applied.

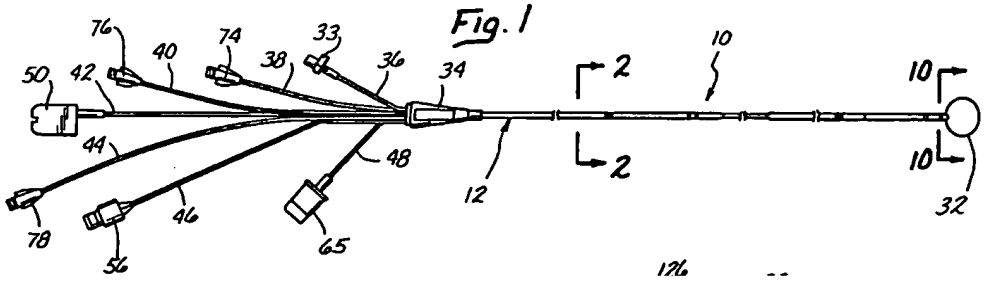
Claim 1 recites in part "*an elongate catheter having a stenosis reducing member, a blood property change port and a downstream sensor spaced from the port for producing a signal corresponding to a blood property.*"

The primary reference Quinn is directed to flotation catheter. (Col. 1, lines 37-38; Col. 1, lines 56-57; Col. 4, lines 26-32) That is, the Quinn balloon is a locating balloon.

While Examiner Szmal recognizes that Quinn fails to disclose the use of the catheter having a stenosis member in order to perform a vascular corrective procedure. To cure this deficiency, the Examiner relies upon Tu *et al.*, to disclose a rapid exchange stented balloon catheter with ablation capabilities. The Examiner asserts since both Quinn and Tu disclose catheters that can be used in vascular corrective procedures it would have been obvious to one

ordinary in the art to modify the device and method of Quinn et al. to include the use of an angioplasty or other corrective procedure as per the teachings of Tu et al. in order to provide a device and method that would allow a cardiac surgeon to determine the blood flow at the site of stenosis and perform corrective procedure with the use of a single catheter instead of changing catheters in order to perform the procedures. [Paper 9, page 3].

However, Quinn is expressly directed to a flotation balloon catheter selected to continuously measure cardiac output and measured mixed venous oxygen saturation. (Col. 1, lines 36-40).



In contrast, Tu is directed to a stented balloon catheter, wherein the catheter includes ablation capabilities. Specifically, a rapid exchange balloon catheter comprised of at least one reversibly collapsible stent having RF abrasion capabilities. (Col. 1., lines 7-10). Tu is further directed to meeting the need for a stented catheter that may be used with the same wire guide that is used to steer the balloon angioplasty catheter.

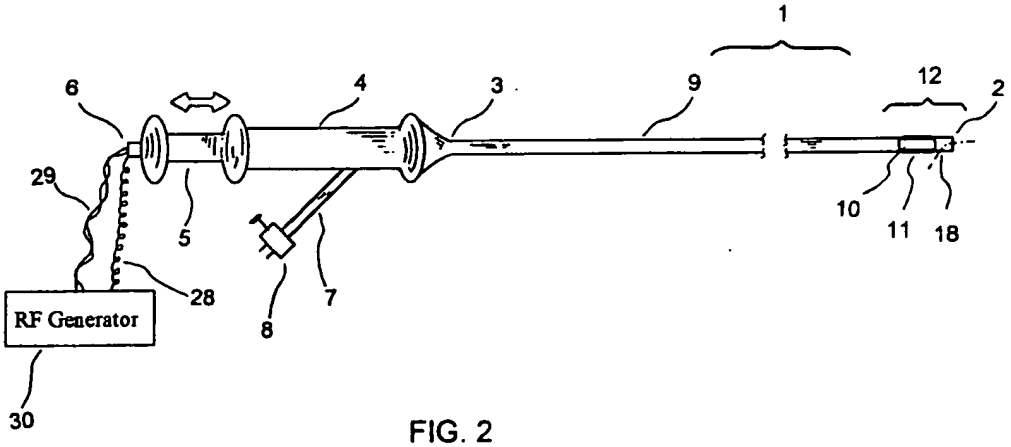


FIG. 2

The outstanding rejection relies upon the proposed interchangeability of a locating balloon and a stenosis reducing member. However, the distinction between locating balloons and stenosis reducing balloons is set forth on page 9, lines 13-25 and page 10, lines 1-23 of the present application. In brief,

> It is understood that locating balloons are used with catheters. These locating balloons are fundamentally different than angioplasty balloons. The locating balloon is an elastic member. Locating balloons are generally spherical and are capable of withstanding just sufficient pressure to partially inflate in the blood flow. Inflation pressures are relatively low, on the order of one psi. *The elastic construction of the locating balloon is such that the balloon may be subject to increased inflation pressure and increased diameter up to failure. The geometry of the locating balloon is selected to allow the balloon (and accompanying catheter) to be carried along a vessel by the blood flow. That is, the geometry of the locating balloon sufficiently increases the hydrodynamic resistance to blood flow to translate the balloon and catheter along the vessel.*
>
> In contrast, an angioplasty balloon is a generally elongate inelastic inflatable member capable of relatively high pressures. *The angioplasty balloon is only expandable to a predetermined size or cross sectional area. Compared to the locating balloon, angioplasty balloons may require inflation pressures greater than 2 psi and as high as 20 psi or greater. The elongate structure of the angioplasty balloon provides for relatively complete contact along the narrowing of the vessel. That is, the spherical locating balloon presents only a point or ring of contact with the surrounding vessel. The angioplasty balloon contacts a length of the vessel to provide relatively constant pressure along the length of contact. In addition, a slight inflation of the locating balloon is used to increase a resistance to blood flow which in turn causes translation of the balloon along the vessel, thereby allowing the locating balloon to the disposed along a vessel. In contrast, a slight inflation of the angioplasty balloon permits flow around and along the balloon and does not create sufficient resistance to flow to induce translation of the balloon (and catheter) along the vessel. Use of a locating balloon to perform angioplasty would allow an elastic balloon to be inflated within the vessel such inflation of an elastic member could rupture the vessel. Alternatively, the elastic member of the locating balloon may not have sufficient strength to displace the vessel wall and perform the angioplasty.* [emphasis added] (Page 9, lines 13-25 and Page 10, lines 1-23 of the present application)

Applicant is unable to find any suggestion in Quinn that the Quinn [locating] device is used "in vascular corrective procedures." Only the Examiners repeated "it would also be obvious" supports the combination asserted by the Examiner in light of the present application.

There is no suggestion in Tu or Quinn to combine a stented balloon angioplasty catheter with a floatation balloon catheter.

"Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [citations omitted] *In re Kotzab*, 217 F.3d 1365, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000)

The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. [citations omitted] *Id.* at 1317.

The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. Broad conclusory statements standing alone are not "evidence." [citations omitted] *Id.* at 1317.

There are no particular findings supporting the position of Examiner Szmal. Applicant respectfully submits the repeated assertion that "It would also have been obvious.." is insufficient. The primary basis for the rejection is the statement "Since both Quinn and Tu disclose catheters that can be used in vascular corrective procedures it would have been obvious to one ordinary in the art to modify the device and method of Quinn et al. to include the use of an angioplasty or other corrective procedure as per the teachings of Tu et al. in order to provide a

device and method that would allow a cardiac surgeon to determine the blood flow at the site of stenosis and perform corrective procedure with the use of a single catheter instead of changing catheters in order to perform the procedures." [Paper 9, page 3]

This statement suffers from a number of frailties. The Examiner equates "a multi-lumen catheter capable of measuring cardiac output continuously, mixed venous oxygen saturation as well as other hemodynamic parameters" with vascular corrective procedures.

The primary reference Quinn is directed to the *continuous* measurement of cardiac output (hence the use of the floatation balloon). Tu is directed to a balloon expanded stent, wherein the flow is temporarily occluded in the vessel. (Col. 1, lines 45-50; Col. 3, lines 9-22 and Figure 3) That is, the Examiner asserts it would be obvious to combine selected components of a device that interrupts flow (Tu) with a device that is directed to continuous measurement (Quinn). The only basis provided by the Examiner is the statement that both references "disclose catheters that can be used in vascular corrective procedures."

While the test for establishing an implicit teaching, motivation or suggestion is what the combination of these two statements of Evans would have suggested to those of ordinary skill in the art, . . . particular findings must be made as the reason the skilled artisan, with no knowledge of the claimed invention would have selected these components for combination in the manner claimed. Kotzab [Absent a specific understanding or principal within the knowledge of the skilled artisan that would have motivated, with no knowledge of the present invention, to make the combination in the claims.]***

"Our case law makes clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for

piecing together the prior art to defeat patentability--the essence of hindsight." [citations omitted] *Ecolochem v. Southern California Edison Co.* 56 USPQ2d 1065, 1073 (Fed. Cir. 2000).

"Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." *Id.* "The opinion then lists each step and states where in the cited prior art references the step can be found. This reference-by-reference, limitation-by-limitation analysis wholly fails to demonstrate how the prior art teaches or suggests the combination claimed in the '411 patent." *Ecolochem*

The Federal Circuit has stated the implicit generalized finding by a district court that when one of ordinary skill was faced with a problem [of the patent] in view of a prior art reference, that the combination claimed would have been obvious is insufficient. *Ecolochem*

"A rejection cannot be predicated on the mere identification of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention would have selected these components for combination in the manner claimed." *Ecolochem*

The outstanding rejection is contrary to a number of the requirements for an obviousness rejection. Specifically:

1. The problem Examiner Szmal alleges to be solved is defined in terms of its solution. That is, the Examiner asserts "Since both Quinn et al. and Tu et al. disclose catheters that can be used in vascular corrective procedures it would have been obvious to one ordinary in the art to modify the device and method of Quinn et al. to include the use of an angioplasty or other corrective procedure as per the teachings of Tu et al. in order to provide a device and method that would allow a cardiac surgeon to determine the blood flow at the site of stenosis and perform corrective procedure with the use of a single catheter instead of changing catheters in order to

perform the procedures." [Paper 9, page 3] This reveals improper hindsight in the selection of the prior art relevant to obviousness.

Further, while Examiner Szmal relies upon the "obviousness" to use a single catheter [Paper 9, page 3], the Examiner states "It would also have been obvious to have separate catheters to perform the corrective procedure and determine the blood flow since it would allow the surgeon to remove the blood flow sensor when the corrective procedure is underway and would also allow for the insertion of the sensor to the stenosis site once the procedure is completed in order to determine the second blood flow rate." [Paper 9, Page 4] Applicant respectfully submits the same references, with the same suggestions to one of ordinary skill in the art, cannot suggest both a single catheter and not a single catheter.

2. Examiner Szmal has not made any showing of a teaching or motivation to combine the prior art references. Seven times the Examiner states "It would also have been obvious to..". However, each justification for the asserted obvious combination is to achieve the claimed invention – and not what the cited references suggest.

3. The final Office Action [Paper 9] does not provide a specific understanding or principal within the knowledge of the skilled artisan that would have motivated, *with no knowledge of the present invention*, to make the combination in the claims. That is, each asserted obvious combination by Examiner Szmal is solely in terms of the present invention, rather than any basis in the cited references for substituting locating balloons and stenosis reducing member.

Not only is there no suggestion to modify Quinn, but to modify Quinn to employ a stenosis reducing member would be expressly contrary to Quinn. That is, the examiner requires one to ignore the reasonable skill in the art and indiscriminately interchange whatever pieces and parts are located in the prior art. That is, the purported interchangeability or modification of

flotation balloon for a stenosis reducing balloon is not obvious to one of ordinary skill in the art. There is no suggestion in Quinn of stenosis reducing members.

Therefore, the rejection of Claim 1 under 35 U.S.C. §103 cannot be sustained.

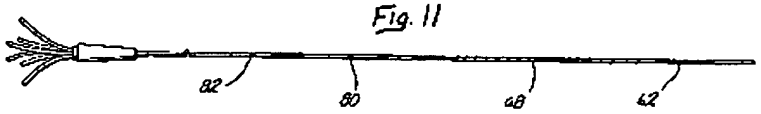
Claim 2

Claim 2 depends from Claim 1 and further recites "one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects."

There is no specific rejection of Claim 2 in Paper 9. For purposes of facilitating a decision on the merits, applicant responds to the examiner's statement "It also would have been obvious to have the ability to locate the sensor with respect to the vessel to minimize wall effects in order to provide an accurate measurement of the blood flow rate without the possibility of an erroneous measurement." [Paper 9, Pages 3-4] applies to Claim 2.

The examiner has not found this limitation in the cited references. The only basis for this obviousness rejection is the examiner's assertion of obviousness. Such level of support cannot satisfy the statutory requirements for a rejection under §103.

The only support applicant is able to identify in Quinn is "Turning to Fig. 11, we see the relative location of the heater 68, the thermistor 62, injectate port 80 and infusion port 82. (Col. 6, Lines 34-35)



As Tu does not disclose the recited sensors, Tu cannot cure the deficiencies of Quinn.

Absent applicant's disclosure, there is no discussion, much less suggestion of configuring one of the sensor in the catheter to minimize wall effects. Therefore, the rejection of Claim 2 under 35 U.S.C. §103 cannot be sustained.

Claim 3

Claim 3 depends from Claim 1 and further recites "a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor."

Examiner Szmal asserts Quinn discloses "means for determining the blood flow rate from the signal generated from the sensor." [Paper 9, Page 2]

However, it would be expressly contrary to employ "a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor" with the stenosis ablation of Tu. That is, the Examiner has selectively taken portions of each reference to support the rejection, without accounting for the full and fair disclosure of each reference. Specifically, why is it obvious to combine the stenosis ablation of Tu (which clearly does not suggest or require a controller for calculating flow rate) with a floatation balloon and sensing of Quinn. Examiner Szmal selects the ablation aspect of Tu, but ignores the fact that flow measurement in conjunction with ablation is contrary to Tu. Further, there is no explanation by the examiner why the device of Quinn for continuously monitoring would be modified with a device that interrupts flow.

Therefore, in view of these distinctions, as well as those set forth with respect to Claim 1, applicant respectfully submits the rejection of Claim 3 under 35 U.S.C. §103 cannot be sustained.

Claim 5

Claim 5, depends from Claim 1 and, recites in part "wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow."

Examiner Szmal states Quinn discloses "the sensor and blood property change port are spaced sufficiently apart to mix the dilution bolus through the port and blood flow." [Paper 9,

Page 2] Examiner Szmal has not identified any portion of Quinn to support this assertion. Again, in an effort to determine the merit of the appeal, applicant assumes the examiner is relying upon the following statement in Quinn:

> At about 26 cm from the distal tip of catheter 10, upstream from thermistor 62, is an injectate port 80, which communicates with injectate lumen 22 or 122. In a preferred embodiment injectate port 80 is located 2 cm proximal to heater 68. As discussed above, injectate port 80 is utilized for injection of a liquid medium to obtain cardiac output values through the bolus thermodilution technique." (Quinn -Col. 6, Lines 59-65)

This passages does not disclose or suggest a spacing of the blood property change port and the sensor to substantially mix a dilution indicator with the flood flow.

Therefore, the rejection of Claim 5 under 35 U.S.C. §103 cannot be sustained.

Claim 8

Claim 8 depends from Claim 7 and recites in part "wherein the correspondence relates blood flow to $= \frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve."

Examiner Szmal has not identified a particular portion of Quinn or Tu, which is relied upon, or can provide the basis of this rejection. Specifically, at Paper 9, Page 4, the examiner merely states "It would have been obvious to utilize the equation for determining the blood flow rate since it can be easily deduced that the volume of the introduced indicator and the area under the dilution curve is related to the blood flow rate."

Applicant again is unable to identify any disclosure or suggestion of the asserted relationship by Examiner Szmal. Further, applicant is unable to identify the specific formula set forth in Equation 8. As such limitations are not present in the cited references are not suggested by the cited references, applicant respectfully submits the rejection of Claim 8 under 35 U.S.C. §103 cannot be sustained.

Claim 9

Independent Claim 9 recites in part,

"(a) a stenosis reducing member selectively actuatable to reduce stenosis in a vessel;

(b) a port for inducing a blood property change; and

(c) a sensor spaced from the blood property change port for providing a signal corresponding to a change in a blood property."

Examiner Szmal has not provided a specific rejection of Claim 9. Therefore, applicant assumes the rejection of Claim 9 is based upon Paper 9, pages 2-4, and hence Claim 9 is unpatentable over Quinn in view of Tu.

Quinn fails to disclose a stenosis reducing member selectively actuatable to reduce stenosis in a vessel. The examiner asserts it would have been obvious to modify Quinn to include the use of an angioplasty or other corrective procedures as per the teaching of Tu.

However, Tu is expressly directed to a stented balloon catheter such that when the balloon of the stented catheter is inflated, the collapsible stent is deformed to an expanded condition to contact the inner wall of the vascular vessel. An external RF generator is provided to supply RF current to the expanded stent to effect the RF ablation. After completing oblation therapy, the balloon is deflated and the stent reversibly collapsed. The stented catheter is withdrawn from the body. (Tu - Col. 3, Lines 42-49)

Further, Tu states in a typical angioplasty procedure once the RF current is provided to the stent for therapeutic purposes, the balloon of the stented catheter is deflated, allowing the stented catheter along the collapsed stent to be withdrawn. The exchange wire guide and the guiding catheter are then withdraw, thereby completing the operation. (Col. 4, Lines 1 and 17-20).

Absent applicant's disclosure, Examiner Szmal has not provided any basis for selecting the ablation characteristics of Tu while ignoring the absurdity of ports or sensors. Further, no basis, outside of the present claims, has been provided for equating or substituting inflation balloons and stenosis reducing members. Again, there is no basis for interrupting flow in a device for continuous monitoring.

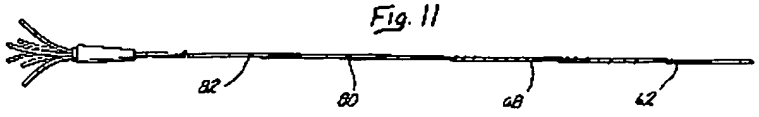
As the asserted combination further fails to satisfy the statutory requirements of §103, applicant respectfully submits the rejection of Claim 9 under 35 U.S.C. §103 cannot be sustained.

Claim 10

Claim 10 depends from Claim 9 and recites in part "wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects."

Although there is no specific discussion of Claim 10 in Paper 9, applicant assumes the asserted basis is the examiner's statement "it also would have been obvious to have the ability to locate the sensor with respect to the vessel to minimize wall effects in order to provide an accurate measurement of the blood flow rate without the possibility of an erroneous measurement." [Paper 9, Pages 3-4]

The examiner has not found the presence of this limitation in the cited references. The only basis for this obviousness rejection is the examiner's assertion. The only support applicant is able to identify in Quinn is "Turning to Fig. 11, we see the relative location of the heater 68, the thermistor 62, injectate port 80 and infusion port 82. (Col. 6, Lines 34-35)



Absent applicant's disclosure, there is no discussion much less suggestion of configuring one of the sensor in the catheter to minimize wall effects. Therefore, the rejection of Claim 10 under 35 U.S.C. §103 cannot be sustained.

Claim 11

Claim 11 depends from Claim 9 and recites in part, "a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor."

Examiner Szmal asserts Quinn discloses "means for determining the blood flow rate from the signal generated from the sensor." [Paper 9, Page 2]

However, it would be expressly contrary to employ "a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor" with the stenosis ablation of Tu. That is, the Examiner has selectively taken portions of each reference to support the rejection, without accounting for the full and fair disclosure of each reference. Specifically, why is it obvious to combine the stenosis ablation of Tu (which clearly does not suggest or require a controller for calculating flow rate) with a floatation balloon and sensing of Quinn. Examiner Szmal selects the ablation aspect of Tu, but ignores the fact that flow measurement in conjunction with ablation is contrary to Tu.

Therefore, in view of these distinctions, as well as those set forth with respect to Claims 1, 3 and 9, applicant respectfully submits the rejection of Claim 11 under 35 U.S.C. §103 cannot be sustained.

Claim 13

Claim 13 depends from Claim 9 and recites in part "the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow."

Examiner Szmal states Quinn discloses "the sensor and blood property change port are spaced sufficiently apart to mix the dilution bolus through the port and blood flow." [Paper 9, Page 2] As Examiner Szmal has not identified a particular aspect of the Quinn patent, applicant assumes the examiner is relying upon the statement in Quinn

> At about 26 cm from the distal tip of catheter 10, upstream from thermistor 62, is an injectate port 80, which communicates with injectate lumen 22 or 122. In a preferred embodiment injectate port 80 is located 2 cm proximal to heater 68. As discussed above, injectate port 80 is utilized for injection of a liquid medium to obtain cardiac output values through the bolus thermodilution technique." (Col. 6, Lines 59-65)

This passages does not disclose or suggest a spacing of the blood property change port and the sensor to substantially mix a dilution indicator with the flood flow.

Therefore, in view of these distinctions, as well as those set forth with respect to the preceding claims, applicant respectfully submits the rejection of Claim 13 under 35 U.S.C. §103 cannot be sustained.

Claim 15

Independent Claim 15 recites in part,

"(a) a dilution indicator source;

(b) a catheter connectable to the dilution indicator source, the catheter having means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough and a downstream sensor for producing a signal corresponding to passage of the dilution indicator; and

(c) a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor."

Examiner Szmal has not provided a specific rejection of Claim 15. Therefore, prior deficiencies of the cited references apply.

Quinn is directed to a flotation balloon catheter and is not directed to reducing stenosis of a vessel. In contrast, Tu is directed to the stenosis of a vessel but does not disclose or suggest dilution indicator sources, ports or controller for determining blood flow. There is no particular

finding why a continuous monitoring device is modified by a device that does not monitor and precludes continuous monitoring. The only basis for combining these references is applicant's disclosure. Therefore, the rejection of Claim 15 under 35 U.S.C. §103 cannot be sustained.

Claim 16

Independent Claim 16 recites a method including, in part:

"(a) inserting a catheter and a blood property sensor into a vessel having a blood flow corresponding to the stenosis;

(b) introducing a first change in a blood property upstream of the blood property sensor;

(c) detecting passage of the first change in the blood property at the blood property sensor;

(d) reducing the stenosis of in the vessel;

(e) introducing a second change in the blood property upstream of the sensor;

(f) detecting passage of the second change in the blood property at the blood property sensor; and

(g) determining a change in blood flow corresponding to the detected passage of the first change in the blood property and the second change in the blood property."

Examiner Szmal has not provided a specific rejection of Claim 16. Applicant assumes the following assertion by the Examiner is the basis for the rejection of Claim 16.

"It would also have been obvious to introduce a second indicator bolus into the blood stream after the stenosis reduction procedure, detecting the indicator bolus, and determining the second blood flow rate and correlating it to the first measured flow rate, since it would allow a cardiac surgeon to determine the effectiveness of the procedure and would allow the surgeon to redo a stenosis corrective procedure if it was deemed that the first procedure was not effective." [Paper 9, Page 4]

However, Quinn fails to disclose limitations d, e, f and g. Tu fails to disclose a, b, c, e, f and g. The asserted reason for the combination is not based on either cited reference, but rather a reconstruction of the purpose of applicant's invention.

The failure of the cited references to disclose the limitations of the claims as well as the lack of independent and particular reason to combine, precludes the rejection of Claim 16 under 35 U.S.C. §103 from being sustained.

Claim 17

Claim 17 depends from Claim 16 and recites in part "wherein inserting a catheter and a blood property sensor into a vessel includes inserting a first catheter having a stenosis reducing member and a second catheter having the blood property sensor."

Examiner Szmal has not identified a particular statement supporting the rejection of Claim 17. Applicant assumes the examiner relies upon "It would also have been obvious to have separate catheters to perform the corrective procedure and determine the blood flow since it would allow the surgeon to remove the blood flow sensor when the corrective procedure is under way and would also allow for the insertion of the sensor to the stenosis site once the procedure is completed in order to determine the second blood flow rate." [Paper 9, Page 4] Examiner Szmal has not identified any section of Quinn or Tu to support the statement.

Yet, Examiner Szmal also states "it would have been obvious to one ordinary in the art to modify the device and method of Quinn et al. to include the use of an angioplasty or other corrective procedure as per the teachings of Tu et al. in order to provide a device and method that would allow a cardiac surgeon to determine the blood flow at the site of stenosis and perform corrective procedure *with the use of a single catheter instead of changing catheters* in order to perform the procedures." [emphasis added] [Paper 9, page 3]

In fact, applicant submits Quinn is expressly contrary to the suggestion of two catheters. Specifically, "the present invention thus provides a catheter which is capable of monitoring various hemodynamic parameter without having to remove and insert numerous catheters or probes with a concomitant risks and inconveniences associated with such multiple procedures." (Col. 2, Lines 13-18)

As the method of Claim 17 is directly contrary to the primary reference and cannot be cured by the secondary reference, applicant respectfully submits the rejection of Claim 17 under 35 U.S.C. §103 cannot be sustained.

Claim 18

Claim 18 depends from Claim 16 and recites in part "wherein inserting a catheter and a blood property sensor into a vessel includes inserting a catheter having a stenosis reducing member and the blood property sensor."

Examiner Szmal does not provide a specific rejection of Claim 18. Applicant assumes the relevant rejection is "It would have been obvious to insert a catheter to a stenosis site that has a stenosis reducing member and the blood flow sensor since it would allow the surgeon to introduce a single catheter into the vessel and perform the procedure, which would also make the procedure less time consuming." [Paper 9, Page 4]

Yet, Examiner Szmal states "*It would also have been obvious to have separate catheters to perform the corrective procedure and determine the blood flow* since it would allow the surgeon to remove the blood flow sensor when the corrective procedure is under way and would also allow for the insertion of the sensor to the stenosis site once the procedure is completed in order to determine the second blood flow rate." [emphasis added] [Paper 9, Page 4]

As the primary reference Quinn does not include a catheter with a stenosis reducing member and the secondary reference Tu does not include a blood property sensor, and the

combination of the claimed structure is not suggested in either reference, the rejection of Claim 18 under 35 U.S.C. §103 cannot be sustained.

Claim 19

Independent Claim 19 recites "A method of monitoring blood flow during a vascular corrective procedure, comprising:

(a) inserting a catheter into a vessel;

(b) employing the catheter to perform a vascular correction in the vessel;

(c) introducing a first blood property change;

(d) detecting passage of the first blood property change past a downstream sensor on the catheter; and

(e) calculating the blood flow in response to the change in blood property and passage of the blood property past the downstream sensor."

Applicant is unable to identify a specific rejection of Claim 19. Applicant assumes the rejection of Claim 19 is based upon the language Examiner Szmal states "It would also have been obvious to insert a catheter to a stenosis site that has a stenosis reducing member and a blood flow sensor since it would allow the surgeon the introduce a single catheter into the vessel and perform the procedure, which would also make the procedure less time consuming." [Paper 9, page 4]

Primary reference Quinn fails to disclose steps a and b. Tu fails to disclose steps c, d, and e. It is contrary to the express purpose of each reference to make the proposed combination.

Further, Examiner Szmal has merely asserted whichever "obvious" variation is required. That is, it is apparently obvious to use one and two catheters in view of the cited references. Therefore, the rejection of Claim 19 under 35 U.S.C. §103 cannot be sustained.

Claim 20

Independent Claim 20 recites "An apparatus for determining blood flow in a vascular passage, comprising:

(a) a catheter having means for increasing the effective size of a portion of the vascular passage, the catheter including a dilution indicator introduction port and a downstream blood property sensor; and

(b) a controller operably connected to the blood property sensor for calculating a flow through the vascular passage corresponding to a signal from the blood property sensor."

Applicant is unable to identify a specific rejection of Claim 20. Therefore, applicant assumes the rejection of Claim 20 is based upon the language "Since both Quinn, *et al.*. and Tu, *et al.*. disclose catheters that can be used in vascular corrective procedures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Quinn, *et al.*. to include the use of an angioplasty or other corrective procedures, as per the teachings of Tu, *et al..*, in order to provide a device and method that would allow a cardiac surgeon to determine the blood flow at the site of stenosis and perform the corrective procedure with the use of a single catheter instead of changing catheters in order to perform the procedure." [Paper 9, Page 3]

Again, this proposed combination impermissibly interchanges floatation balloons and stenosis reducing members. In addition, the purported reason for the combination is found in the present application, rather than either of the cited references. Therefore, the rejection of Claim 20 under 35 U.S.C. §103 cannot be sustained.

Claim 21

Claim 21 depends from Claim 20 and further recites "wherein the controller determines the flow corresponding to the relation $AF = \frac{V}{\int C(t)dt}$ where AF corresponds to the flow, V is a volume of indicator introduced and $\int C(t)dt$ is the area under a dilution curve."

Examiner Szmal has not identified a particular aspect of Quinn or Tu, which is relied upon to provide the basis of this rejection. However, at Paper 9, Page 4, the examiner states "It

would have been obvious to utilize the equation for determining the blood flow rate since it can be easily deduced that the volume of the introduced indicator and the area under the dilution curve is related to the blood flow rate."

Applicant again is unable to identify any disclosure or suggestion of the asserted relationship by Examiner Szmal. Further, applicant is unable to identify the specific formula set forth in Equation 21. As such limitations are not present in the prior are nor suggested by the cited references, applicant respectfully submits the rejection of Claim 21 under 35 U.S.C. §103 cannot be sustained.

Claim 22

Independent Claim 22 recites "An apparatus for determining an intra-procedural blood flow in a vascular corrective procedure, comprising:

(a) a catheter;

(b) a blood parameter altering section on the catheter;

(c) means for effecting the corrective produce; and

(d) a blood parameter sensor connected to the catheter and spaced from the altering section."

Examiner Szmal has not set forth a particular rejection of Claim 22. Applicant assumes the basis of the rejection is: "Since both Quinn, *et al.*. and Tu, *et al.*. disclose catheters that can be used in vascular corrective procedures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Quinn, *et al.* to include the use of an angioplasty or other corrective procedures, as per the teachings of Tu, *et al.*, in order to provide a device and method that would allow a cardiac surgeon to determine the blood flow at the site of stenosis and perform the corrective procedure with the use of a single catheter instead of changing catheters in order to perform the procedure." [Paper 9, Page 3]

Again, the combination asserted by Examiner Szmal fails to account for the inherent distinctions between floatation balloons and stenosis reducing members. In addition, the

Examiner has not provided any basis, absent the present disclosure, for the selective picking and choosing of certain limitations, without addressing the exclusion of expressly related structure. It would be contrary to Quinn to interrupt the continuous monitoring. Therefore, the rejection of Claim 22 under 35 U.S.C. §103 cannot be sustained.

Claim 24

Claim 24 depends from Claim 22 and further recites "a controller connectable to the altering section and the blood parameter sensor to calculate the blood flow."

Examiner Szmal asserts Quinn discloses "means for determining the blood flow rate from the signal generated from the sensor." [Paper 9, page 2]

However, it would be expressly contrary to employ "a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor" with the stenosis ablation of Tu. That is, the Examiner has selectively taken portions of each reference to support the rejection, without accounting for the full and fair disclosure of each reference. Specifically, why is it obvious to combine the stenosis ablation of Tu (which clearly does not suggest or require a controller for calculating flow rate) with a floatation balloon and sensing of Quinn. Examiner Szmal selects the ablation aspect of Tu, but ignores the fact that flow measurement in conjunction with ablation is contrary to Tu. Also, rendering the primary reference to be contrary to its express purpose cannot be an obvious variation.

Therefore, in view of these distinctions, as well as those set forth with respect to the preceding claims, applicant respectfully submits the rejection of Claim 24 under 35 U.S.C. §103 cannot be sustained.

Claim 25

Independent Claim 25 recites "A method of monitoring a stenosis reducing procedure in a vessel, comprising:

(a) locating a blood parameter altering section in the vessel;

(b) locating a blood parameter sensor downstream of the altering section;

(c) performing the stenosis reducing procedure; and

(d) determining a blood flow in response to a passage of an altered blood property past the blood parameter sensor."

Examiner Szmal has not set forth a specific rejection of Claim 25. Therefore, applicant assumes the basis of the rejection lies in "It would also have been obvious to insert a catheter to a stenosis site that has a stenosis reducing member and a blood flow sensor since it would allow the surgeon the introduce a single catheter into the vessel and perform the procedure, which would also make the procedure less time consuming." [Paper 9, Page 4]

Not only is this asserted combination not supported by the cited references, it impermissibly relies upon the present application and is therefore hindsight. Only by selectively picking and choosing from the references (and ignoring the stated purpose of each reference) is the examiner's combination possible. Quinn cannot perform stenosis reducing procedures, and to modify Quinn to prevent continuous monitoring is contrary to Quinn. Therefore, the rejection of Claim 25 under 35 U.S.C. §103 cannot be sustained.

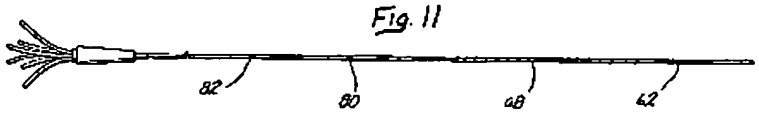
Claim 27

Claim 27 depends from Claim 25 and further recites "locating the blood parameter sensor to reduce wall effects from the vessel."

There is no specific rejection of Claim 27 in Paper 9. For purposes of facilitating a decision on the merits, applicant assumes the examiner's statement "It also would have been obvious to have the ability to locate the sensor with respect to the vessel to minimize wall effects in order to provide an accurate measurement of the blood flow rate without the possibility of an erroneous measurement." [Paper 9, Pages 3-4]

The examiner has not found this limitation in the cited references. The only basis for this obviousness rejection is the examiner's assertion of obviousness. Such level of support cannot satisfy the statutory requirements for a rejection under §103.

The only support applicant is able to identify in Quinn is "Turning to Fig. 11, we see the relative location of the heater 68, the thermistor 62, injectate port 80 and infusion port 82. (Col. 6, Lines 34-35)



Absent applicant's disclosure, there is no discussion, much less suggestion of configuring one of the sensor in the catheter to minimize wall effects. Therefore, the rejection of Claim 27 under 35 U.S.C. §103 cannot be sustained.

Claim 28

Claim 28 depends from Claim 25 and further recites "rotating the blood parameter sensor with respect to the vessel to reduce wall effects from the vessel."

There is no specific rejection of Claim 27 in Paper 9. For purposes of facilitating a decision on the merits, applicant assumes the examiner's statement "It also would have been obvious to have the ability to locate the sensor with respect to the vessel to minimize wall effects in order to provide an accurate measurement of the blood flow rate without the possibility of an erroneous measurement." [Paper 9, Pages 3-4]

As there is no disclosure in either the primary reference or the secondary reference to minimizing wall effects, it cannot be obvious rotate the blood parameter sensor to minimize wall effects. Therefore, the rejection of Claim 28 under 35 U.S.C. §103 cannot be sustained.

Claim 30

Claim 30 depends from Claim 1 and further recites in part, "the sensor detects changes in one of electrical impedance and electrical resistance."

Examiner Szmal has not identified a specific instance of this limitation in Quinn, but rather asserts Quinn discloses "the sensor detects one of optical, thermal, electrical, chemical of physical property of the blood." [Paper 9, page 2]

Applicant is unable to locate any mention in Quinn of measuring electrical impedance or electrical resistance. Therefore, applicant respectfully submits the primary reference fails to disclose the asserted structure. As the structure is not present in the cited reference and there is no independent basis for the inclusion, the rejection of Claim 30 under 35 U.S.C. §103 cannot be sustained.

Claim 32

Claim 32 depends from Claim 9 and recites in part, "the sensor detects changes in one of electrical impedance and electrical resistance."

Examiner Szmal has not identified a specific instance of this limitation in Quinn, but rather asserts Quinn discloses "the sensor detects one of optical, thermal, electrical, chemical of physical property of the blood." [Paper 9, page 2]

Applicant is unable to locate any mention in Quinn of measuring electrical impedance or electrical resistance. Therefore, applicant respectfully submits the primary reference fails to disclose the asserted structure. As the structure is not present in the cited reference and there is no independent basis for the inclusion, the rejection of Claim 32 under 35 U.S.C. §103 cannot be sustained.

Therefore, applicant respectfully submits all the pending claims, Claims 1-33 are in condition for allowance, and requests the outstanding rejection under 35 U.S.C. §103 be reversed.

Respectfully submitted

Brian B. Shaw, Registration No. 33,782
Harter, Secrest & Emery LLP
700 Midtown Tower
Rochester, New York 14604-2070
(716) 232-6500

Date: December 29, 2000

Appendix

1. An apparatus for determining a blood flow in a vessel, comprising:

(a) an elongate catheter having a stenosis reducing member, a blood property change port and a downstream sensor spaced from the port for producing a signal corresponding to a blood property.

2. The apparatus of Claim 1, wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

3. The apparatus of Claim 1, further comprising a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor.

4. The apparatus of Claim 1, wherein the blood property change port includes an aperture for introducing a blood property variant.

5. The apparatus of Claim 1, wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

6. The apparatus of Claim 1, wherein the blood property change port includes one of a heat sink and a heat source for creating a local temperature gradient.

7. The apparatus of Claim 1, wherein the signal from the sensor corresponds to a blood flow in the vessel.

8. The apparatus of Claim 7, wherein the correspondence relates blood flow to $= \frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

9. A stenosis reducing catheter, comprising:

(a) a stenosis reducing member selectively actuatable to reduce stenosis in a vessel;

(b) a port for inducing a blood property change; and

(c) a sensor spaced from the blood property change port for providing a signal corresponding to a change in a blood property.

10. The catheter of Claim 9, wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

11. The catheter of Claim 9, further comprising a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor.

12. The catheter of Claim 9, wherein the port includes an aperture for introducing a blood property variant.

13. The catheter of Claim 9, wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

14. The catheter of Claim 9, wherein the port includes one of a heat sink and a heat source for creating a local temperature gradient.

15. An apparatus for determining blood flow, comprising:

(a) a dilution indicator source;

(b) a catheter connectable to the dilution indicator source, the catheter having means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough and a downstream sensor for producing a signal corresponding to passage of the dilution indicator; and

(c) a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor.

16. A method for quantitatively measuring a reduced stenosis induced flow change, comprising:

(a) inserting a catheter and a blood property sensor into a vessel having a blood flow corresponding to the stenosis;

(b) introducing a first change in a blood property upstream of the blood property sensor;

(c) detecting passage of the first change in the blood property at the blood property sensor;

(d) reducing the stenosis of in the vessel;

(e) introducing a second change in the blood property upstream of the sensor;

(f) detecting passage of the second change in the blood property at the blood property sensor; and

(g) determining a change in blood flow corresponding to the detected passage of the first change in the blood property and the second change in the blood property.

17. The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a first catheter having a stenosis reducing member and a second catheter having the blood property sensor.

18. The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a catheter having a stenosis reducing member and the blood property sensor.

19. A method of monitoring blood flow during a vascular corrective procedure, comprising:

(a) inserting a catheter into a vessel;

(b) employing the catheter to perform a vascular correction in the vessel;

(c) introducing a first blood property change;

(d) detecting passage of the first blood property change past a downstream sensor on the catheter; and

(e) calculating the blood flow in response to the change in blood property and passage of the blood property past the downstream sensor.

20. An apparatus for determining blood flow in a vascular passage, comprising:

(a) a catheter having means for increasing the effective size of a portion of the vascular passage, the catheter including a dilution indicator introduction port and a downstream blood property sensor; and

(b) a controller operably connected to the blood property sensor for calculating a flow through the vascular passage corresponding to a signal from the blood property sensor.

21. The apparatus of Claim 20, wherein the controller determines the flow corresponding to the relation $AF = \frac{V}{\int C(t)dt}$ where AF corresponds to the flow, V is a volume of indicator introduced and $\int C(t)dt$ is the area under a dilution curve.

22. An apparatus for determining an intra-procedural blood flow in a vascular corrective procedure, comprising:

(a) a catheter;

(b) a blood parameter altering section on the catheter;

(c) means for effecting the corrective produce; and

(d) a blood parameter sensor connected to the catheter and spaced from the altering section.

23. The apparatus of Claim 22, wherein the blood altering section includes one of a port and a temperature gradient generator.

24. The apparatus of Claim 22, further comprising a controller connectable to the altering section and the blood parameter sensor to calculate the blood flow.

25. A method of monitoring a stenosis reducing procedure in a vessel, comprising:

(a) locating a blood parameter altering section in the vessel;

(b) locating a blood parameter sensor downstream of the altering section;

(c) performing the stenosis reducing procedure; and

(d) determining a blood flow in response to a passage of an altered blood property past the blood parameter sensor.

26. The method of Claim 25, wherein performing the stenosis reducing procedure includes angioplasty.

27. The method of Claim 25, further comprising locating the blood parameter sensor to reduce wall effects from the vessel.

28. The method of Claim 25, further comprising rotating the blood parameter sensor with respect to the vessel to reduce wall effects from the vessel.

29. The method of Claim 25, further comprising locating a plurality of blood parameter sensors in the vessel.

30. The apparatus of Claim 1, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

31. The apparatus of Claim 1, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

32. The catheter of Claim 9, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

33. The catheter of Claim 9, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.